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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,177	09/26/2003	John Lezdey	1435-1	9860

7590 06/16/2006

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Pinellas Park, FL 33782

EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,177

Applicant(s)

LEZDEY ET AL.

Examiner

Nancy T. Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-12 are pending in the case.

Sequence compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences are set forth in the specification (for examples see pages 16, 17) that lack sequence identifiers. If the sequences are already present in the sequence listing, it would be remedial to amend the specification to include the appropriate sequence identifiers. Applicants are required to comply with all of the requirements of 37 CFR 1.821 - 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F. R. 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

Claim Objections

Claims 2, 3, 4, 9, 10, 11, 12 are objected to because of the following informalities: In claim 2, "alpha mating factors" presumably should read "alpha mating factor". In claim 3, "secretin" presumably should be "secretion", and "to" should be inserted before "said promoter" in the last line of the claim. In claim 4, "a" should be

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inserted before "target sequence" in line 2 of the claim. In claim 9, "the" should be inserted before "AOX1 sequence". In claim 10, "to" should be inserted after "linked" in line 6 of the claim. In claim 11, "the" should be inserted before "expression vector". The claims should be carefully reviewed to be corrected for any further grammatical errors. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, and by dependence claims 2-9, are vague and indefinite in the recitation of "a promoter obtained from a methanol responsive gene of *Pichia pastoris* at a pH of about 5 to 6.8". It is not clear from the claim whether applicants intend the pH to refer to the media pH in which the recited yeast strain is grown, or whether the pH refers to the pH at which the recited gene is methanol responsive.

Claim 10 is vague and indefinite in reciting "(ii) introducing expression of the alpha1-antitrypsin coding sequence from the expression vector to produce alpha1-antitrypsin..." , since it is not clear how "expression" is introduced. (It may be that applicants intended the term "inducing").

Claim 11 recites an expression vector which is "pGPICZ". However, the specification does not contain any description or recitation of pGPICZ, and it is unclear what is intended by this term. The specification does however recite "pPICZ", which may be what the applicants intended.

Claim 12 recites "selected from the group consisting of KM71, and SMD1168H said strains comprising a...". It is unclear what is intended by this phrase. The claim is further vague and indefinite in the recitation of "a sequence of nucleotides encoding alpha1-antitrypsin and a promoter region from Pichia pastoris AOX1 gene operably linked to the sequence of nucleotides that encodes glycosylated alpha1-antitrypsin", since it is not clear that the sequence encoding alpha1-antitrypsin is intended to be the same as the sequence encoding glycosylated alpha1-antitrypsin. Claim 12 is further vague and indefinite in the recitation of "comprising the steps of ..." since it appears that only one step, i.e. culturing, is recited. Therefore the intended metes and bounds cannot be determined.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

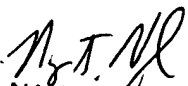
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
6/9/06


NANCY VOGEL
PRIMARY EXAMINER